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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/803,954	02/21/1997	KEITH E. LANGLEY	0109063/004	9382

22852 7590 05/20/2003

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
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1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER

HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
08/803,954

Applicant(s)
Langley et al

Examiner
Robert C. Hayes, Ph.D.

Art Unit
1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 20, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-67 is/are pending in the application.
- 4a) Of the above, claim(s) 57-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 53-67 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1647

DETAILED ACTION

Response to Amendment

1. The amendment filed 2/20/03 has been entered.
2. The rejection of claim 53 under 35 U.S.C. 101 for being directed to non-statutory subject matter is withdrawn due to the amendment of the claim.
3. The rejection of claims 53-56 under 35 U.S.C. 112, first paragraph, for lack of written description is withdrawn due to the amendment of the claims.
4. The rejection of claims 53-56 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn due to the amendment of the claims.
5. Applicant's arguments filed 2/20/03 have been fully considered but they are not deemed to be persuasive.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1647

7. This application contains claims 57-67 drawn to an invention nonelected with traverse in Paper No. 37. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

8. Applicants are again reminded that because parent application no. 07/355,027 is at the Board of Appeals, and because the Examiner does not have access to the pending claims on appeal, a double patenting rejection may be necessitated if those claims are directed toward antibodies of metalloproteinase inhibitor products, as in the instant application.

9. The Declaration filed on 2/20/03 under 37 CFR 1.131 has been considered but is ineffective to overcome the rejection under 35 U.S.C. 102(e) as being unpatentable over Stetler-Stevenson et al. (U.S. Patent 5,595,885).

In contrast to Declarants' assertions, no exhibits were submitted establishing that Declarants were in possession of that disclosed in US Patent '885. Therefore, the evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81

Art Unit: 1647

O.G. 1417 (D.C. Cir. 1897). Thus, the declaration is defective, in accordance with MPEP 715.02.

10. Claims 53-54, 55 & 56 are rejected under 35 U.S.C. 102(e) as being unpatentable over Stetler-Stevenson et al. (U.S. Patent 5,595,885), in light of Clark et al., and for the reasons made of record in Paper No: 38 (mailed 6/3/02), and as follows.

In summary, Stetler-Stevenson et al. teach antibodies made to the CSC-21K/TIMP-2 metalloproteinase inhibitor protein (e.g., col. 6, lines 43-67; col. 10, lines 24-32; col. 16, lines 34-58), in which specific peptide sequences/epitopes are described to make monoclonal antibodies (i.e., as it inherently relates to both the bovine and human TIMP-2 polypeptides in claims 53-54). For example, epitopes CSCSPVHPQQAFCA and SLNHRYQQGCECKITRCP are identical in both the polypeptides of SEQ ID NOs: 7 & 9, and the epitope MIPCYISSPDEC-LWTD is different by only a single amino acid residue near the C-terminal end of TIMP-2. In particular, note that lines 43-58 disclose that an “antibody binding site consists of a sequence of from four to six amino acids”. Therefore, because the bovine and human sequences of SEQ ID NOs: 7 & 9, respectively, share more than “four to six [common] amino acid sequences”, Stetler-Stevenson’s antibodies would reasonably and inherently react with both the polypeptides of SEQ ID NOs: 7 & 9, as claimed; absent evidence to the contrary. In that hybridoma cells are first required to be made, in order to generate such monoclonal antibodies, the limitations of claim 56 are also reasonably met by the teachings of Stetler-Stevenson; absent evidence to the contrary. In

Art Unit: 1647

that column 10 (lines 30-31) disclose that “[t]hese antibodies are reactive on standard western and immunoblots”, column 16 (lines 33-44) disclose that “CSC-21... antibodies... are also useful in diagnosis of diseases characterized by abnormal balances of matrix metalloproteinase and associated inhibitor”, in which “[s]uitable immunoassays for CSC-21 could include anti-CSC-21 antibodies” and reasonably would be “tagged with suitable enzymatic, fluorescent or radioactive labels by means well known in the art”, especially when it is routine in the art to label antibodies for ELISA or Western assays (e.g., see Clark et al., pages 167, 169-170, 174-175 & 176), the limitation of claim 55 for “comprising a detectable label” is also reasonably anticipated by Stetler-Stevenson.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1647

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to be 'RCH' with a checkmark-like flourish at the end.

Robert C. Hayes, Ph.D.
May 6, 2003